

AMENDMENTS TO THE SPECIFICATION

Please amend the paragraph beginning at page 5, line 8 as follows:

The stabilization method of the invention can be applied to stabilize the active for the purposes of storage, handling, and/or transport. The stabilizing substances absorb or chemically bind water molecules fast and strong enough to prevent water absorption to the surface of particles of the active pharmaceutical ingredient. In accordance with the invention any one of the following or mixtures thereof or mixture comprising it can be added to the active as a stabilizing substance: magnesium oxide or calcium oxide or silicon dioxide or ~~polyethyleneglycol~~ polyethyleneglycol or croscarmellose sodium. The silicon dioxide can be colloidal silicon dioxide, for example as sold under the trade name Aerosil, or anhydrous silicon dioxide, preferably in the form of a finely divided silicon dioxide, for example as sold under the trade name ~~Syloid~~ Syloid™ or can be in a synergistic intimate physical mixture with another substance. Silicified microcrystalline cellulose, for example as sold under trade name Prosolv is such mixture of two components; microcrystalline cellulose and colloidal silicon dioxide.

Please amend the paragraph beginning at pages 5, line 22 as follows:

Coloidal silicon dioxide is preferably of small particle size and large specific surface area with desirable flow characteristics-those needed to improve the flow properties of dry powders in processes, e.g., tableting. Finely divided silicon dioxide is a preferred stabilizing substance according to the present invention and is an amorphous powder characterized by an internal structure of sponge like pores. Several grades of commercially available Syloid™ silicon dioxide are characterized by the porosity, average particle size, and the surface treatment. Preferably finely divided silicon dioxide has small particles bellow 20, um, fine pores and large specific area above 250m2/g. The preferred grade Syloid AL-1 silicon dioxide has an average particle size 6.0-7. 6 um (Malvern), BET surface area is 750m2/g and is not surface treated, however silicon dioxide can be treated with an organic coating i.e. with a wax.

Please amend the paragraph beginning at page 11, line 16 as follows:

The following inactive ingredients are used: ~~Syloid™~~ Syloid™ silicon dioxide (anhydrous colloidal silicon dioxide), magnesium oxide, PVP K-25 (polivinylpyrrolidone), PEG 6000 (polyethyleneglycol), anhydrous lactose, Ac-di-sol (croscarmellose sodium), magnesium stearate, Prosolv (silicified microcrystalline cellulose), Aerosil (anhydrous colloidal silicon dioxide)

Please amend the paragraph beginning at page 14, line 1 as follows:

The results demonstrate that in mixtures with ~~Syloid™~~ Syloid™ silicon dioxide and PEG 6000 the API remains in the initial polymorph form after 4 days in vials, and under more demanding conditions, after 5 days at constant 60 % relative humidity, not more than 1-2 % conversion into form I occur. The stabilisation effect occurs even though water content increases up to 3.5-7%. Surprisingly in an equivalent experiment using PVP K-25 instead of PEG 6000 the initial polymorph completely converts into form I after 4 days in the vial.